



# UNITED STATES PATENT AND TRADEMARK OFFICE

*[Signature]*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,250	06/21/2005	Malcolm Carter	3890-1000-000	2767
959	7590	09/07/2007		
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER KIFLE, BRUCK	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,250	<b>Applicant(s)</b> CARTER ET AL.	
	<b>Examiner</b> Bruck Kifle, Ph.D.	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26,31-41 and 43-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-26,31-34 and 43-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/05, 08/05, 08/07</u> . | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Applicant's election without traverse of group V, claims 35-41, in the reply filed on 08/16/07 is acknowledged.

Claims 1-26, 31-34 and 43-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/16/07.

***Claim Rejections - 35 USC § 112***

Claims 35-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) In the independent claims, it is suggested to replace the phrase "benzodiazepine derivative of formula (Ib)" with "compound of formula (Ib)" because the metes and bounds of a benzodiazepine derivative could not be ascertained. Similarly, in the dependent claims, replacing the phrase "benzodiazepine derivative" with "compound" is suggested. The structural formula and definition of the variables fully defines the compound claimed.
- ii) The term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.
- iii) The term "heterocyclyl" is indefinite because it is not known how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended.

Art Unit: 1624

iv) The term “carbocyclyl” is indefinite because it is not known how many atoms make up the ring and what kind of a ring is intended (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.).

v) The claims are presented in contradictory terms. For example,  $R^{5/}$  is defined as heteroaryl. However, later in the claim,  $R^{5/}$  is excluded from being 6-chloro-pyrazinyl. It is not possible to exclude whatever was not included in the first place. This is not possible because  $R^{5/}$  is not permitted to have a halo substituent. The group  $R^{5/}$  is defined as heteroaryl which means just that and not an optionally halogen substituted heteroaryl. There are numerous instances similar to this situation in the claims.

There are too many compounds excluded from the generic claims to run an efficient search. Applicants are urgently requested to point to these compounds in the prior art because the disclosure of these compounds is material to the examination of this application. Applicants are requested to point to each excluded compound in a given reference.

Claim 41 is an independent claim and has about 65 independent species. This number of compounds cannot be considered a reasonable number according to rule 1.140(a). In re Fressola, 22 USPQ 2nd 1828, indicates that the Examiner may reject for Applicants failure to follow a Rule. The claim is not according to the rules.

See MPEP rule 1.141(a) reproduced below.

1.141 Different inventions in one national application.

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim

Art Unit: 1624

generic to all the claimed species and all the claims to species in excess of one are written in dependent form ( 1.75) or otherwise include all the limitations of the generic claim.

### ***Claim Rejections - 35 USC § 102***

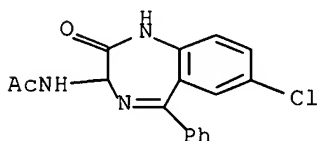
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (US 3,344,136). The claims read on the compound below.

IT 4173-63-1P  
 RL: SPN (Synthetic preparation); PREP (Preparation) (preparation of)  
 RN 4173-63-1 CAPLUS  
 CN Acetamide, N-(7-chloro-2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl)- (8CI, 9CI) (CA INDEX NAME)



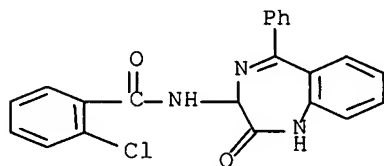
This compound corresponds to the compounds in the claims when in the instant case, n=1, R<sup>1</sup> is aryl, R<sup>2</sup> is hydrogen, R<sup>3</sup> is halogen, R<sup>4</sup> is hydrogen and R<sup>5/</sup> is X', X' is -CO-R<sup>6</sup> and R<sup>6/</sup> is C<sub>1</sub> alkyl

Claims 35 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Freidinger et al. (EP 167919). The claims read on the compounds in Table 4, page 60. These compounds, copied below for Applicants convenience, correspond to compounds of claim 35 when in the instant case, n=0, R<sup>1</sup> is aryl, R<sup>2</sup> is hydrogen, R<sup>4</sup> is hydrogen and R<sup>5/</sup> is -CO-R<sup>6</sup> and R<sup>6/</sup> is aryl.

Art Unit: 1624

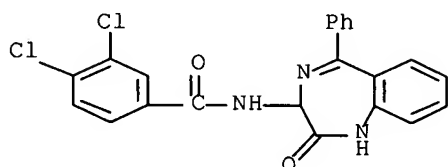
RN 103373-17-7 CAPLUS

CN Benzamide, 2-chloro-N-(2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl)-(9CI) (CA INDEX NAME)



RN 103373-21-3 CAPLUS

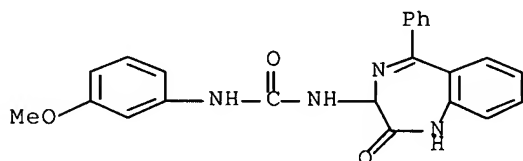
CN Benzamide, 3,4-dichloro-N-(2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl)-(9CI) (CA INDEX NAME)



Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (EP 284256). The claim reads on the compound 745 in page 109. This compound, copied below for Applicants convenience, correspond to compounds of claim 40 when in the instant case R' is aryl substituted by alkoxy.

RN 119506-69-3 CAPLUS

CN Urea, N-(2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl)-N'-(3-methoxyphenyl)-(9CI) (CA INDEX NAME)

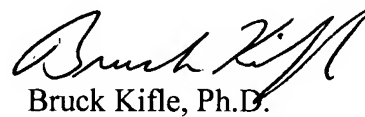


Copious amount was found during the search that render the claims obvious based on the excluded compounds. Thus, ring position isomers, homologues and differences in the length of alkylene linking claims of the excluded compounds render the instant claims obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached on Mondays-Fridays from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bruck Kifle, Ph.D.  
Primary Examiner  
Art Unit 1624

BK  
August 29, 2007